



PATENT
Customer No. 22,852
Attorney Docket No. 6832.0015

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Craig A. ROSEN et al.) Group Art Unit: 1653
Application No.: 09/833,117) Examiner: Hope A. Robinson
Filed: April 12, 2001)
For: ALBUMIN FUSION PROTEINS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement dated August 26, 2003, the Examiner required restriction under 35 U.S.C. § 121 between:

Group I: Claims 1-21 drawn to an albumin fusion protein comprising a therapeutic protein X (SEQ ID NO:) and albumin (SEQ ID NO: 18), classified in class 424, subclass 192.1;

Group II: Claims 22-25, drawn to a method of treating a disease or disorder in a patient, classified in class 514, subclass 12;

Group III: Claim 26, drawn to a method of extending the shelf life of Therapeutic protein X (SEQ ID NO:), classified in class 435, subclass 449;

Group IV: Claims 27-29, drawn to a nucleic acid molecule, classified in class 536, subclass 23.4;

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Group V Claims 30-50 and 59, drawn to an albumin fusion protein comprising IL-2, classified in class 424, subclass 192.1;

Group VI Claims 51-54, drawn to a method of treating a disease or disorder in a patient using the fusion protein comprising IL-2, classified in class 514, subclass 12;

Group VII Claim 55, drawn to a method of extending the shelf life of IL-2, classified in class 435, subclass 449; and

Group VIII Claims 56-58, drawn to a nucleic acid molecule encoding an albumin fusion protein comprising IL-2, classified in class 536, subclass 23.4.

Applicants provisionally elect to prosecute Group I, claims 1-21 drawn to an albumin fusion protein comprising a therapeutic protein X (SEQ ID NO:) and albumin (SEQ ID NO: 18), with traverse.

According to MPEP § 803, there are two requirements that must be met before a proper restriction requirement may be made: (1) the inventions must be independent or distinct as claimed; and (2) there must be a serious burden on the Examiner if restriction is not required. Applicants respectfully submit that the Office has failed to establish the second requirement set forth in MPEP § 803.

In the present invention, Group I is directed to an albumin fusion protein comprising a therapeutic protein X and albumin. Group II is directed to a method of treating a disease or disorder comprising the step of administering the albumin fusion protein as defined in Group I. Additionally, Group IV is directed to a nucleic acid molecule encoding the albumin fusion protein as defined in Group I. Groups V-VIII

parallel Groups I-IV except that Groups V-VIII are directed to an albumin fusion protein comprising IL-2. A search and examination of the subject matter of Group I would encompass a search for the subject matters of Groups II and IV, and any additional search would not impose a serious burden upon the Examiner. Likewise, a search of Group V would encompass a search for the subject matters of Groups VI and VIII.

It is therefore respectfully requested that the restriction requirement be reconsidered. In the event that the restriction requirement is maintained, Applicants reserve the right to file divisional applications on the non-elected inventions and/or to request rejoinder of appropriate claims once the subject matter of claims 1-21 is found allowable.

Applicants have also filed a Change of Correspondence Address herewith.

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Please grant any extensions of time required to enter this response and charge
any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: September 17, 2003

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